MAY 2 3 2000

K000974

Section 9. SMDA 510(k) Summary

24 March 2000

Trade Name:	EndoCurette
Common Name:	Uterine Curette
Classification:	Obstetric-gynecologic specialized manual instrument, 21 CFR 884.4530 (a)(4)

The EndoCurette™, designed by R. Stuart Fowler, M.D. and marketed by Utah Medical Products, Inc., is a tissue sampling curette used by gynecologists in their offices to extract endometrial lining of the uterus for histologic analysis, without the need for dilation of the cervix or the use of general anesthetic. The EndoCurette is substantially equivalent to the Unimar® Pipelle® that is marketed by CooperSurgical, as well as several other devices.

The device consists of an injection molded thermoplastic curetting tip that is bonded to a cannula. The cannula serves as a receiving section for excised tissue. A plunger inside the cannula is drawn back to produce a vacuum which draws excised endometrial tissue into the receiving section of the cannula. The plunger is then used to extrude the collected tissue into a container for transport to a laboratory for analysis.

Although there are slight differences in the dimensions and physical configuration of the curetting tips of the EndoCurette and the predicate devices including the Pipelle, the methods of use, materials, and intended use are substantially the same. Laboratory and clinical tests of the EndoCurette have demonstrated that it is as safe and effective for obtaining samples of the endometrial lining as the predicate devices.

Kevin L. Cornwell
Chairman & CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Mr. Kevin L. Cornwell
Chairman & CEO
Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047-1048

Re: K000974
Fowler Endocurette, Model CUR-XXX
Dated: March 24, 2000
Received: March 27, 2000
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HHK

Dear Mr. Cornwell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Section 3. INTENDED USE/ INDICATIONS for USE

510(k) Number:_____

Device Name: EndoCurette

Intended Use:
The use of the EndoCurette, a single patient use device, is intended for obtaining endometrial tissue samples for histological assessment, per 21 CFR §884.4530 (a)(4), when indicated for use. The intended use is the same as the intended use of the predicate devices listed in Section 8, Substantial Equivalence.

Indications for use:

- Persistent abnormal or dysfunctional uterine bleeding in a woman over age 35, or prolonged amenorrhea in a premenopausal woman of any age.
- Postmenopausal bleeding.
- At the time of starting hormone replacement therapy in an obese woman (especially with estrone effect on the vaginal mucosa), or a woman with late menopause, nulliparity, diabetes, hypertension, or family history of uterine cancer.
- Breakthrough bleeding persisting beyond or occurring after 8-12 months of continuous combined hormone replacement therapy (consider sooner if significant risk factors exist).
- Intermenstrual bleeding in women on cyclic-sequential or cyclic-combined hormone replacement therapy.
- Persistent breakthrough bleeding despite one or two courses of supplemental estrogen in women who are long-term users of oral contraceptives.
- Determination of endometrial tissue response to hormonal influences.
- Abnormal bleeding in women on tamoxifen therapy.
- Detection of precancerous conditions and follow-up surveillance in women who have undergone treatment for endometrial hyperplasias.

Please refer also to Section 6, Labeling.

_____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,**
and Radiological Devices
510(k) Number K020974

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)